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Attorneys for Plaintiff and Counter-Defendant
I-FLOW CORPORATION

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

I-FLOW Corporation, a Delaware corporation Plaintiff, v. Zone Medical LLC, a California limited liability company, Defendant.	Civil Action No. 08cv0057 DMS (NLS) **DECLARATION OF BORIS ZELKIND IN SUPPORT OF PLAINTIFF'S MOTION TO CONSOLIDATE** Date: April 11, 2008 Time: 1:30 p.m. Courtroom 10, 2nd Floor Honorable Dana M. Sabraw

I, Boris Zelkind, declare and state as follows:

1. I am a partner in the law firm of Knobbe, Martens, Olson & Bear, LLP, counsel of record for Plaintiff I-Flow Corporation ("I-Flow") in this action. I submit this declaration in Support of Plaintiff's Motion to Consolidate. The following statements are based on my personal knowledge unless otherwise indicated.

2. Attached hereto as Exhibit 1 is a true and correct copy of the Second Amended Complaint for Patent Infringement; Trade Secret Misappropriation; Breach of Confidence; and Common Law and Statutory Unfair Competition against Apex Medical Technologies, Inc. and Mark McGlothlin (referred to jointly as "APEX"), filed January 14, 2008.

3. The related case against APEX is currently progressing through claim construction discovery pursuant to the Patent Local Rules. The parties have submitted Preliminary Infringement Contentions and Preliminary Invalidity Contentions; and have exchanged Preliminary Claim Constructions.

4. On or about January 10, 2008, I-Flow filed a patent infringement action against Zone Medical, LLC ("Zone"). I-Flow filed suit after learning that Zone markets the SOLACE™ Post-Operative Pain Relief Infusion System ("Accused Solace Pump"). I-Flow filed a notice of related cases identifying the litigation against APEX in this judicial district contemporaneously with the complaint.

5. In this action, I-Flow has accused Zone of marketing the Accused Solace Pump in violation of the '481 patent. The '481 patent is at issue in both this case and the related case against APEX. Likewise, the same accused product, the Accused Solace Pump, is at issue in both cases.

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6. The parties met and conferred regarding consolidation of the related cases. I-Flow sought Zone's consent to file a joint motion to consolidate. Zone has refused to stipulate to consolidation of the related cases.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on March 6, 2008 in San Diego, California.

Boris Zelkind

EXHIBIT 1

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Attorneys for Plaintiff and Counter-Defendant
I-FLOW CORPORATION

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

I-FLOW CORPORATION, a Delaware corporation, Plaintiff, v. APEX MEDICAL TECHNOLOGIES, INC., a California corporation; MARK MCGLOTHLIN, an Individual, Defendants.	Case No. 3:07-cv-1200 DMS (NLS) **SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT; TRADE SECRET MISAPPROPRIATION; BREACH OF CONFIDENCE; AND COMMON LAW AND STATUTORY UNFAIR COMPETITION** **DEMAND FOR JURY TRIAL**
APEX MEDICAL TECHNOLOGIES, INC., a California corporation, Counter-Claimant, v. I-FLOW CORPORATION, a Delaware corporation, Counter-Defendant.	

Plaintiff I-FLOW CORPORATION ("I-FLOW") hereby complains of Defendants APEX MEDICAL TECHNOLOGIES, INC. ("Apex") and MARK MCGLOTHLIN ("McGlothlin") (referred to jointly as "Defendants"), and alleges as follows:

JURISDICTION AND VENUE

1. This action arises under the Patent Laws of the United States, Title 35 of the United States Code.

2. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338, and 1367.

3. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

THE PARTIES

4. Plaintiff I-FLOW is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 20202 Windrow Drive, Lake Forest, CA 92630.

5. I-FLOW is informed and believes, and thereon alleges, that Defendant Apex is a corporation organized and existing under the laws of the State of Illinois, having a place of business in this district at 10064 Mesa Ridge Court, Suite 202, San Diego, CA 92121.

6. I-FLOW is informed and believes, and thereon alleges, that Defendant McGlothlin is an individual residing in San Diego County, California, and is the President and CEO of Defendant Apex.

7. I-FLOW is informed and believes, and thereon alleges, that all Defendants conduct business throughout the United States, including in this Judicial District, and have committed the acts complained of in this Judicial District and elsewhere.

ALLEGATIONS FOR ALL CLAIMS FOR RELIEF

8. On February 8, 1994, the U.S. Patent and Trademark Office ("PTO") duly and lawfully issued U.S. Patent No. 5,284,481 entitled "Compact Collapsible Infusion Apparatus" (the "'481 patent"). I-FLOW is the owner by assignment of the '481 patent. On September 11, 2006, I-FLOW provided a copy of the '481 patent to Defendants. A copy of the '481 patent is attached hereto as Exhibit A.

9. Defendants' SOLACE™ Post-Operative Pain Relief Infusion System includes an infusion pump (the "SOLACE™ Infusion Pump") that is covered by the '481 patent.

10. I-FLOW is informed and believes, and thereon alleges, that Defendant Apex, through its agents, employees and servants, has infringed I-FLOW'S patent rights through its making, using, selling, importing and/or offering to sell infusion pumps such as the SOLACE™ Infusion Pump. Furthermore, this infringement has been willful, Defendant Apex having received actual notice of I-FLOW's patent rights.

11. I-FLOW is informed and believes, and thereon alleges, that Defendant McGlothlin, through his agents, employees and servants, has personally directed or participated in infringing I-FLOW'S patent rights by personally directing or participating in the making, using, selling, importing and/or offering to sell infusion pumps such as the SOLACE™ Infusion Pump. Furthermore, this infringement has been willful, Defendant McGlothlin having received actual notice of I-FLOW's patent rights.

12. I-FLOW is informed and believes, and thereon alleges, that Defendant McGlothlin participated in The Adaptive Business Leaders Organization (ABL), an advisory group of which I-FLOW's principal is a member. I-FLOW is further informed and believes, and thereon alleges, that Defendant McGlothlin agreed to maintain the confidentiality of any confidential and proprietary information obtained in the course of his participation in the ABL. In the course of Defendant McGlothlin's participation in the ABL, Defendants gained access to I-FLOW's confidential business information regarding the infusion pump and drug delivery markets, including, but not limited to, business and marketing strategies, market analysis and product development strategies (hereinafter referred to as "Confidential Business Information"). I-FLOW's Confidential Business Information includes proprietary information.

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13. Defendants and I-FLOW engaged in a collaborative development effort during the calendar year 2005. In the course of this collaborative development effort, I-FLOW disclosed to Defendants, pursuant to obligations of secrecy, confidential technical information regarding I-FLOW's infusion pump technology, including, but not limited to, product specifications and requirements, methods of manufacturing, design challenges and other technical know-how (hereinafter referred to as "Confidential Technical Information"). I-FLOW's Confidential Technical Information includes proprietary information.

14. Defendants gained access to I-FLOW's Confidential Technical Information upon promising to maintain the secrecy of such information, as follows: "[Apex] shall consider all information furnished by [I-Flow] to be confidential and shall not disclose any such information to any other person, or use such information itself for any purpose other than the performing of the contract." Defendants also agreed not to "release to any person, details, specifications, drawings, blueprints or design of any article or component hereof which have been supplied to [Apex] by [I-Flow] and which components have been manufactured by [Apex] to [I-Flow's] specifications."

15. I-FLOW is informed and believes, and on that basis alleges, that Defendant Apex makes, uses, sells and offers for sale pain management devices, including, but not limited to, the SOLACE™ Post-Operative Pain Relief Infusion System.

16. I-FLOW is informed and believes, and on that basis alleges, that Defendant McGlothlin, through his agents, employees and servants, personally directs or participates in Apex's making, using, selling and offering for sale pain management devices, including, but not limited to, the SOLACE™ Post-Operative Pain Relief Infusion System.

17. I-FLOW is informed and believes, and on that basis alleges that Defendants have misused and continue to misuse I-FLOW's Confidential Business Information and Confidential Technical Information, obtained under obligations of secrecy and confidentiality for the purpose of developing Defendants' own business to unfairly compete with I-FLOW.

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18. I-FLOW is informed and believes, and on that basis alleges that Defendants, without authorization, have misappropriated and continue to misappropriate proprietary information included in I-FLOW's Confidential Business Information and Confidential Technical Information, obtained under obligations of secrecy and confidentiality for the purpose of developing Defendants' own competing business.

19. I-FLOW is informed and believes, and on that basis alleges that Defendants have used and disclosed and continue to use and disclose I-FLOW's Confidential Business Information and Confidential Technical Information, in willful and conscious disregard of a duty of confidence owed to I-FLOW.

20. I-FLOW is informed and believes, and on that basis alleges, that Defendants have committed and continue to commit unlawful business practices including, but not limited to, using I-FLOW's Confidential Business Information and Confidential Technical Information for Defendants' own purposes, and adversely to the interests of I-FLOW and its business venture.

21. By the aforesaid acts of Defendants, I-FLOW has been greatly damaged, and will continue to be irreparably damaged unless Defendants are enjoined by the Court.

FIRST CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 5,284,481)

22. I-FLOW repeats, realleges, and incorporates by reference the allegations set forth in paragraphs 1 through 21 of this Complaint.

23. This is a claim for patent infringement and arises under the Patent Laws of the United States, Title 35 of the United States Code.

24. I-FLOW is informed and believes, and thereon alleges, that Defendant Apex, through its agents, employees and servants, has been and is currently willfully and intentionally infringing the '481 patent by making, using, selling, importing and/or offering to sell infusion pumps, such as the SOLACE™ Infusion Pump, that are covered by at least one claim of the '481 patent. Defendant Apex's acts constitute infringement of the '481 patent in violation of 35 U.S.C. § 271.

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25. I-FLOW is informed and believes, and thereon alleges, that Defendant McGlothlin, through his agents, employees and servants, has been and is currently willfully and intentionally infringing the '481 patent by personally directing or participating in the making, using, selling, importing and/or offering to sell infusion pumps, such as the SOLACE™ Infusion Pump, that are covered by at least one claim of the '481 patent. Defendant McGlothlin's acts constitute infringement of the '481 patent in violation of 35 U.S.C. § 271.

26. I-FLOW is informed and believes, and thereon alleges, that Defendants' infringement will continue unless enjoined by this Court.

27. I-FLOW is informed and believes, and thereon alleges, that Defendants have derived and received, and will continue to derive and receive, gains, profits and advantages from the aforesaid acts of infringement in an amount that is not presently known to I-FLOW. By reason of the aforesaid infringing acts, I-FLOW has been damaged and is entitled to monetary relief in an amount to be determined at trial.

28. Because of the aforesaid infringing acts, I-FLOW has suffered and continues to suffer great and irreparable injury, for which I-FLOW has no adequate remedy at law.

SECOND CAUSE OF ACTION

(TRADE SECRET MISAPPROPRIATION)

29. I-FLOW hereby realleges and incorporates by reference the allegations set forth in paragraphs 1 through 28.

30. This is a cause of action for Misappropriation of Trade Secrets under the Uniform Trade Secrets Act, Cal. Civ. Code § 3426 *et seq.*, based upon Defendant's wrongful and improper use and disclosure of proprietary information contained within I-FLOW's Confidential Business Information and Confidential Technical Information.

31. The proprietary information contained within I-FLOW's Confidential Technical Information is trade secret because it derives independent economic value from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use.

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32. Defendants gained access to I-FLOW's Confidential Technical Information in the course of a collaborative development effort between the parties. Defendants were under an obligation to maintain the secrecy of the Confidential Techinical Information obtained during the parties' collaboration.

33. The proprietary information contained within I-FLOW's Confidential Business Information is trade secret because it derives independent economic value from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use.

34. Defendants gained access to I-FLOW's Confidential Business Information in the course of Defendant McGlothlin's participation in the ABL, and such access to I-FLOW's Confidential Business Information was subject to confidentiality agreements. I-FLOW is informed and believes, and thereon alleges, that Defendants were under a duty to not use for their benefit or disclose the confidential information learned in the course of participation in the ABL.

35. I-FLOW took reasonable precautions under the circumstances to protect its trade secrets, and all parties with access to the information were subject to obligations to maintain its secrecy.

36. I-FLOW is informed and believes, and thereon alleges, that Defendants have and continue to use and disclose to third parties I-FLOW's trade secrets without I-FLOW's consent or permission, in attempting to develop Defendants' own competing business.

37. I-FLOW is informed and believes, and thereon alleges, that Defendants have disclosed I-FLOW's trade secrets to third parties, maliciously and in willful and conscious disregard of the rights of I-FLOW.

38. As a direct and proximate result of Defendants' willful, improper, and unlawful use and disclosure of I-FLOW's trade secrets, I-FLOW has and will continue to suffer great harm and damage. I-FLOW will continue to be irreparably damaged unless Defendants are enjoined from further use and disclosure of I-FLOW's trade secret information.

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39. I-FLOW is informed and believes, and thereon alleges, that the aforementioned acts of Defendants in wrongfully misappropriating I-FLOW's trade secrets, were and continue to be willful and malicious, warranting an award of exemplary damages, as provided by Civ. Code § 3426.3(c), and an award of reasonable attorneys fees, as provided by Civ. Code § 3426.4.

THIRD CAUSE OF ACTION

(BREACH OF CONFIDENCE)

40. I-FLOW hereby realleges and incorporates by reference the allegations set forth in paragraphs 1 through 39.

41. This is a cause of action for Breach of Confidence under California common law.

42. When I-FLOW disclosed its non-trade secret Confidential Business Information to Defendant McGlothlin, it did so in confidence in the course of participating in a professional advisory organization. Members of the ABL, including Defendant McGlothlin, undertake a confidentiality obligation, and, therefore, Defendants owed I-FLOW a legal duty of confidence to maintain the non-trade secret Confidential Business Information in a confidential manner, and not to use the non-trade secret Confidential Business Information for Defendants' own purposes.

43. Defendants accepted the non-trade secret Confidential Business Information as alleged herein voluntarily and while Defendant McGlothlin was participating in a professional advisory organization, thereby owing I-FLOW a duty of confidence with respect to I-FLOW's non-trade secret Confidential Business Information.

44. I-FLOW provided its non-trade secret Confidential Technical Information to Defendants in confidence for the purpose of furthering a collaborative development effort. Defendants undertook to maintain I-FLOW's non-trade secret Confidential Technical Information in confidence and to use it only for the purpose of the collaborative effort. Therefore, Defendants owed I-FLOW a legal duty of confidence to maintain the non-trade secret Confidential Technical Information in a confidential manner, and not to use the non-trade secret Confidential Technical Information for Defendants' own purposes.

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45. Defendants accepted the non-trade secret Confidential Technical Information as alleged herein voluntarily and for the purpose of furthering a collaborative development effort, thereby owing I-FLOW a duty of confidence with respect to I-FLOW's non-trade secret Confidential Technical Information.

46. I-FLOW is informed and believes, and thereon alleges, that Defendants have willfully and in conscious disregard for the duty of confidence owed to I-FLOW, used for Defendants' own purposes and disclosed to others I-FLOW's non-trade secret Confidential Business Information and/or non-trade secret Confidential Technical Information.

47. As a direct and proximate result of Defendants' willful, improper, and unlawful use and disclosure of I-FLOW's non-trade secret Confidential Business Information and non-trade secret Confidential Technical Information, I-FLOW has and will continue to suffer great harm and damage. I-FLOW will continue to be irreparably damaged unless Defendants are enjoined from further use and disclosure of I-FLOW's non-trade secret Confidential Business Information and non-trade secret Confidential Technical Information.

48. I-FLOW is informed and believes, and thereon alleges, that the aforementioned acts of Defendants, in breaching their duty of confidence owed to I-FLOW, were and continue to be willful and malicious, warranting an award of punitive damages in addition to the actual damages suffered by I-FLOW

FOURTH CAUSE OF ACTION

(UNFAIR COMPETITION)

49. I-FLOW hereby realleges and incorporates by reference the allegations set forth in paragraphs 1 through 48.

50. This is a cause of action for Unfair Competition under the California common law.

51. The acts of Defendants, alleged herein, including, but not limited to, Defendants' misuse of I-FLOW's non-trade secret Confidential Business Information and non-trade secret Confidential Technical Information for the purposes of developing Defendants' own business to compete with that of I-FLOW, constitutes unlawful, unfair, and fraudulent business practices in violation of the California common law of Unfair Competition.

52. I-FLOW is informed and believes, and thereon alleges, that Defendants have willfully and in conscious disregard for I-FLOW's rights and its business, committed unfair and unlawful business practices including, but not limited to, using for Defendants' own purposes, and adversely to the interests of I-FLOW and its business venture, I-FLOW's non-trade secret Confidential Business Information and non-trade secret Confidential Technical Information.

53. As a direct and proximate result of Defendants' willful, improper, and unlawful use and disclosure of I-FLOW's non-trade secret Confidential Business Information and non-trade secret Confidential Technical Information, I-FLOW has and will continue to suffer great harm and damage. I-FLOW will continue to be irreparably damaged unless Defendants are enjoined from further committing unfair and unlawful business practices against I-FLOW and I-FLOW's business.

FIFTH CAUSE OF ACTION

(STATUTORY UNFAIR COMPETITION)

54. I-FLOW hereby realleges and incorporates by reference the allegations set forth in paragraphs 1 through 53.

55. This is a cause of action for Statutory Unfair Competition under California Bus. & Prof. Code § 17200, et seq.

56. The acts of Defendants alleged herein, including, but not limited to, Defendants' misuse of I-FLOW's non-trade secret Confidential Business Information and non-trade secret Confidential Technical Information for the purpose of developing Defendants' own business to compete with that of I-FLOW, constitutes unlawful, unfair, and fraudulent business practices in violation of California Bus. & Prof. Code § 17200, et seq.

57. As a direct and proximate result of Defendants' willful, improper, and unlawful use and disclosure of I-FLOW's non-trade secret Confidential Business Information and non-trade secret Confidential Technical Information, I-FLOW has and will continue to suffer great harm and damage. I-FLOW will continue to be irreparably damaged unless Defendants are enjoined from further committing unfair and unlawful business practices against I-FLOW and I-FLOW's business.

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PRAYER FOR RELIEF

WHEREFORE, I-FLOW prays for judgment in its favor against Defendants for the following relief:

A. An Order adjudging Defendants to have willfully infringed the '481 patent under 35 U.S.C. § 271;

B. An injunction enjoining Defendants, their respective officers, directors, agents, servants, employees and attorneys, and those persons in active concert or participation with Defendants, from directly or indirectly infringing the '481 patent in violation of 35 U.S.C. § 271;

C. That Defendants account for all gains, profits, and advantages derived by Defendants' infringement of the '481 patent in violation of 35 U.S.C. § 271, and that Defendants pay to I-FLOW all damages suffered by I-FLOW since at least February 8, 1994;

D. An Order for a trebling of damages and/or exemplary damages because of Defendants' willful conduct pursuant to 35 U.S.C. § 284;

E. An Order adjudging that this is an exceptional case;

F. An award to I-FLOW of the attorneys' fees and costs incurred by I-FLOW in connection with this action pursuant to 35 U.S.C. § 285;

G. An award of pre-judgment and post-judgment interest and costs of this action against Defendants;

H. That Defendants be adjudged to have misappropriated I-FLOW's trade secrets in violation of the Uniform Trade Secrets Act, Cal. Civ. Code § 3426 *et seq.*, and that Defendants' actions in doing so be adjudged willful and malicious;

I. That Defendants be adjudged to have breached their duty of confidence owed to I-FLOW under the common law of the State of California, and that Defendants' acts in doing so be adjudged willful and malicious;

J. That Defendants be adjudged to have competed unfairly with I-FLOW under the common law of the State of California;

K. That Defendants be adjudged to have competed unfairly with I-FLOW under California Business and Professions Code § 17200, and that Defendants' actions in doing so be adjudged willful and done knowingly;

L. That Defendants, their respective agents, servants, employees and attorneys, and all those persons in active concert or participation with it, be forthwith preliminarily and thereafter permanently enjoined, pursuant to 35 U.S.C. § 283 and California Business and Professions Code § 17200 from further disclosing to any third parties any of I-FLOW's Confidential Business Information and Confidential Technical Information and unfairly competing with I-FLOW in any manner;

M. That Defendants be directed to file with this Court and serve on Plaintiff within thirty (30) days after the service of the injunction, a report in writing, under oath, setting forth in detail the manner and form in which Defendants have complied with the injunction;

N. That Defendant be required to account to I-FLOW for any and all gains, profits and advantages derived by it, and all damages sustained by I-FLOW, by reason of Defendants' acts complained herein, including Defendants' breach of confidence and Defendants' common law and statutory unfair competition;

O. That the Court deem this case exceptional under 15 U.S.C. § 1117 and award I-FLOW reasonable attorneys' fees; and

P. Such other and further relief as this Court may deem just.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 14, 2008

By: s/Boris Zelkind
Steven J. Nataupsky
Boris Zelkind
Ali S. Razai

Attorneys for Plaintiff and Counter-Defendant
I-FLOW CORPORATION

DEMAND FOR TRIAL BY JURY

I-FLOW CORPORATION hereby demands a trial by jury on all issues so triable.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 14, 2008

By: s/Boris Zelkind
Steven J. Nataupsky
Boris Zelkind
Ali S. Razai

Attorneys for Plaintiff and Counter-Defendant
I-FLOW CORPORATION

CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2008, I caused the **SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT; TRADE SECRET MISAPPROPRIATION; BREACH OF CONFIDENCE; AND COMMON LAW AND STATUTORY UNFAIR COMPETITION** to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following person(s):

Ralph B. Kalfayan, Esq.
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rkalfayan@kkbs-law.com

Norbert Stahl, Esq.
STAHL LAW FIRM
nstahl@patentlawservice.com

I certify and declare under penalty of perjury under the laws of the State of California that I am employed in the office of a member of the bar of this Court at whose direction the service was made, and that the forgoing is true and correct.

Executed on January 14, 2008, at San Diego, California.

Megan Ptacin

IFLOWL.241L

US005284481A

United States Patent [19]

Soika et al.

[11] **Patent Number: 5,284,481**

[45] **Date of Patent: Feb. 8, 1994**

[54] **COMPACT COLLAPSIBLE INFUSION APPARATUS**

[75] Inventors: **Emil H. Soika**, Poway; **Steven R. Payne**, San Diego, both of Calif.

[73] Assignee: **Block Medical, Inc.**, Carlsbad, Calif.

[21] Appl. No.: **984,899**

[22] Filed: **Dec. 2, 1992**

[51] **Int. Cl.**[5] **A61M 37/00**

[52] **U.S. Cl.** **604/132**; 206/438; 206/370; 222/105

[58] **Field of Search** 604/132, 133, 140, 142, 604/153; 222/105, 106, 107, 103, 95; 206/438, 363, 370, 820, 461, 462, 571; 128/DIG. 12

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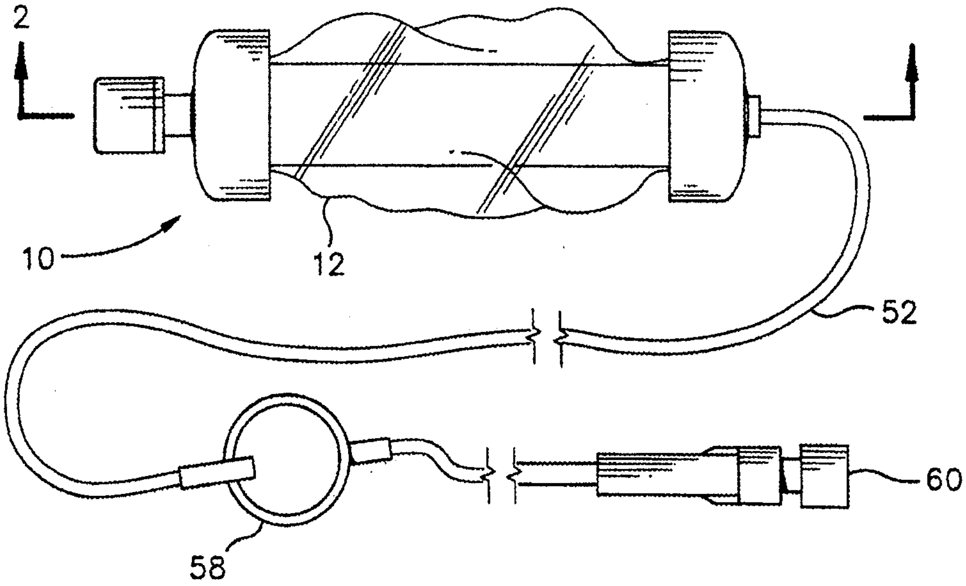
Primary Examiner—John G. Weiss
Attorney, Agent, or Firm—Baker, Maxham, Jester & Meador

[57] **ABSTRACT**

A liquid infuser apparatus includes an elastic sleeve mounted on an elongated member and within a collapsible spherical housing to enable it to expand naturally to maintain a constant pressure over the infusion period. A rigid open ended housing into which an infuser may be removeably placed provides a reusable protective housing. Multiple infusers are packaged with a rigid housing in a kit.

28 Claims, 5 Drawing Sheets



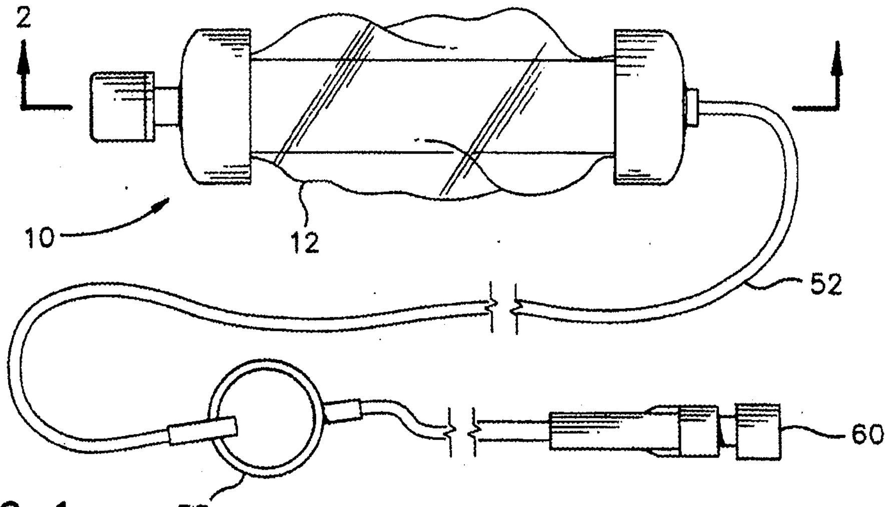

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FIG. 1

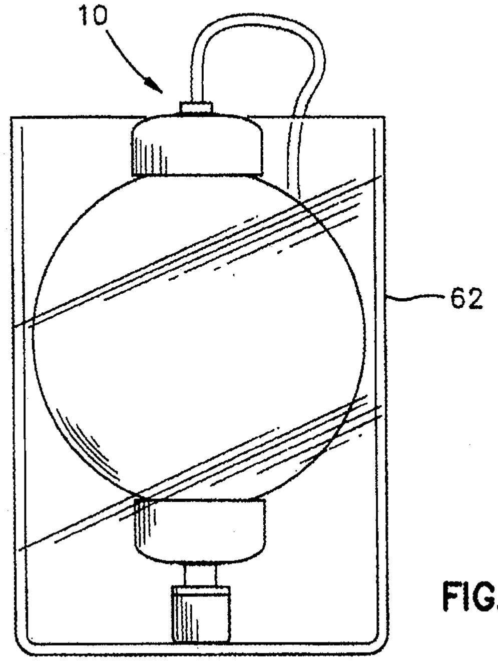

FIG. 6

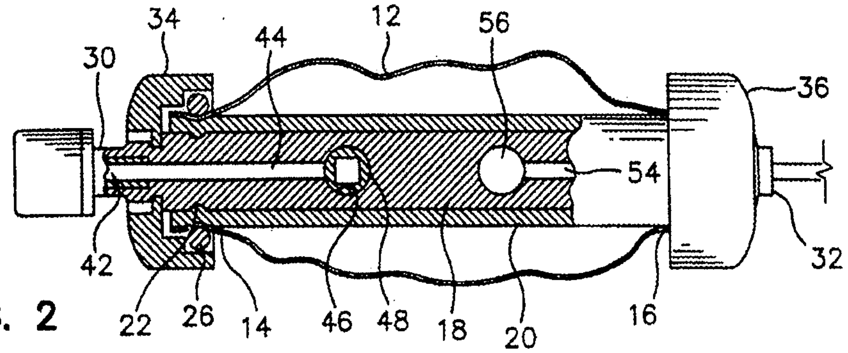
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FIG. 2

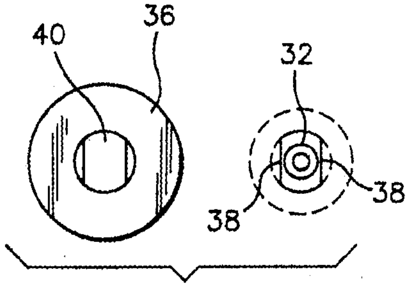
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FIG. 3

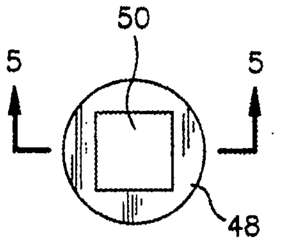

FIG. 4

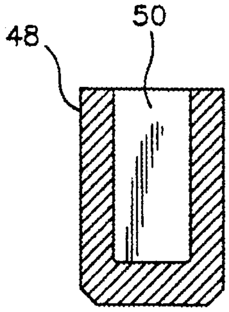

FIG. 5

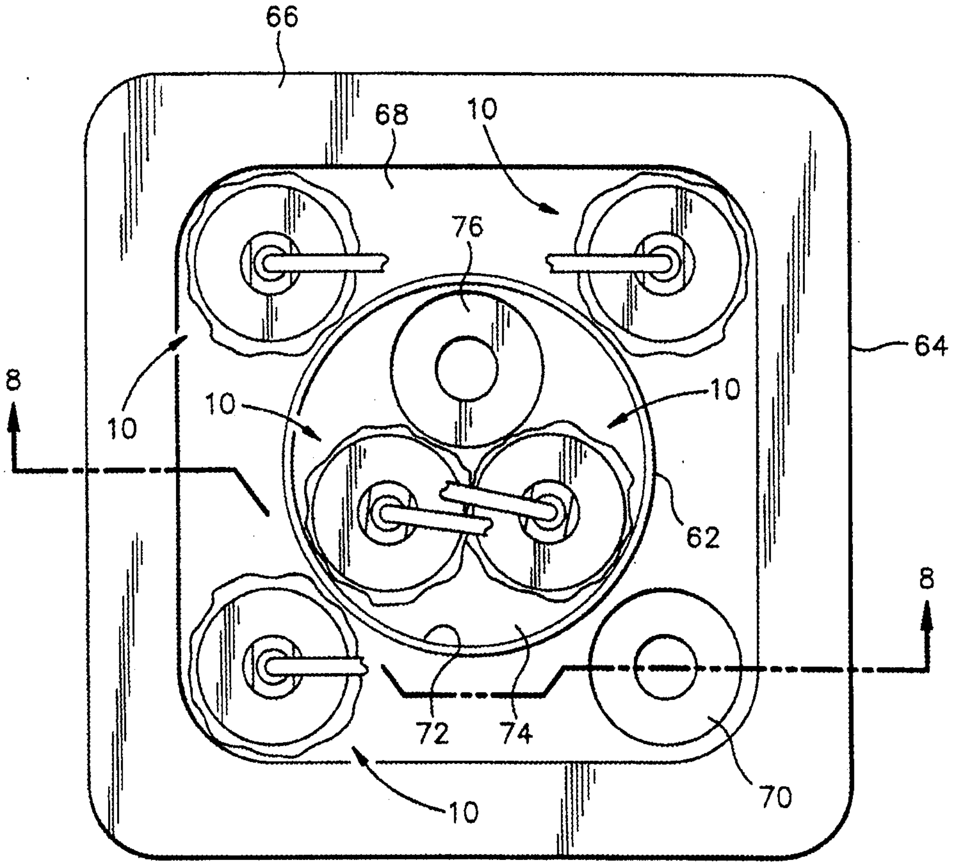
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FIG. 7

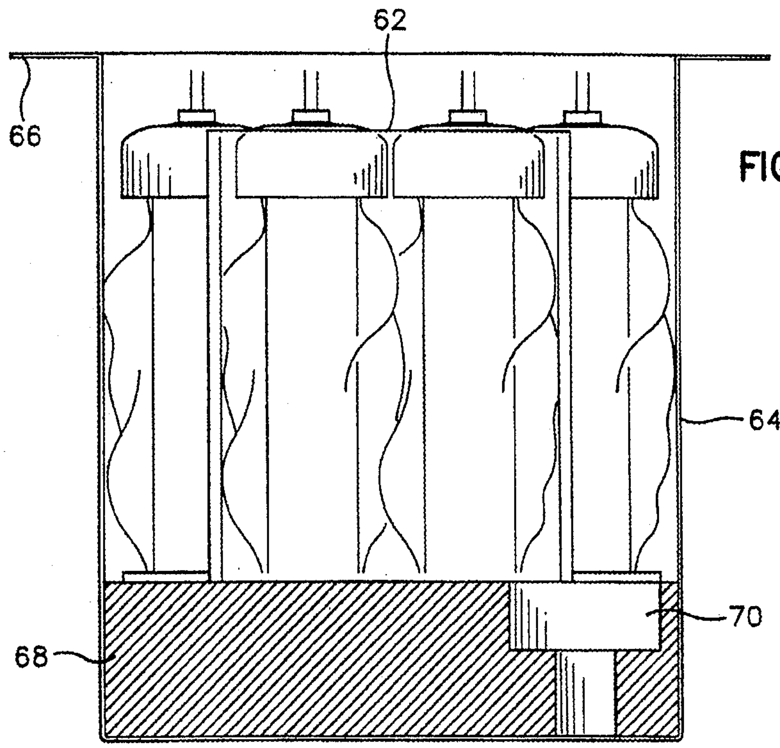

62
66
64
70
68

FIG. 8

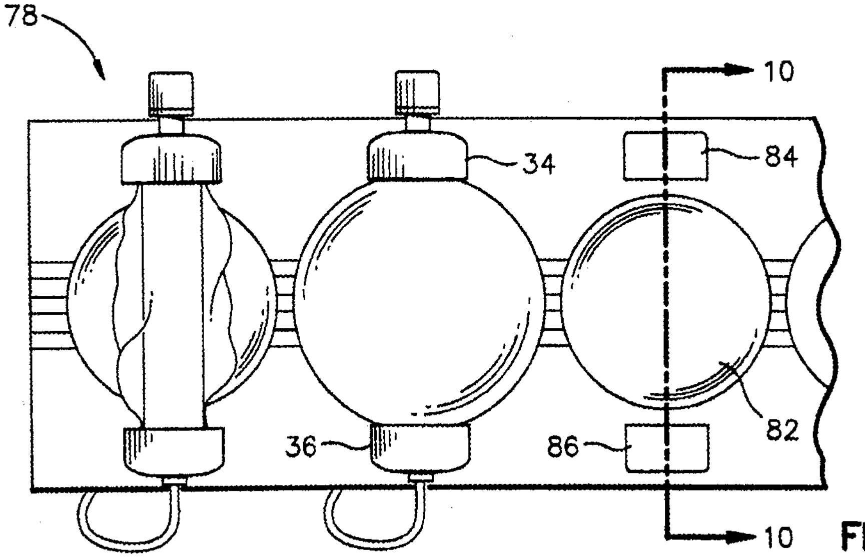
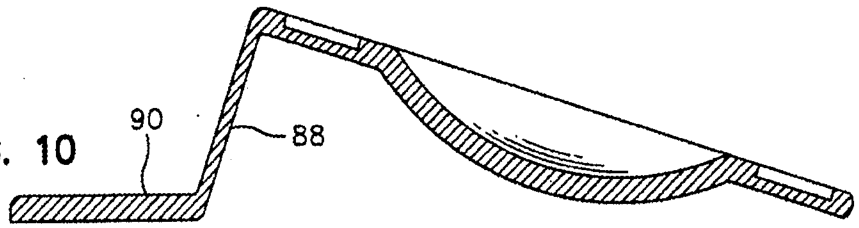

78
10
34
84
82
36
86
10

FIG. 9

FIG. 10



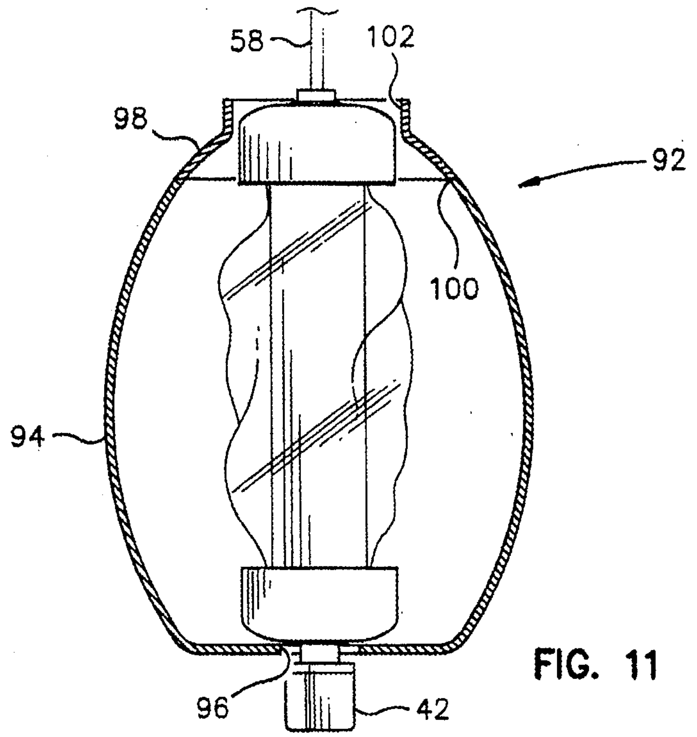

58
102
98
92
100
94
96
42

FIG. 11

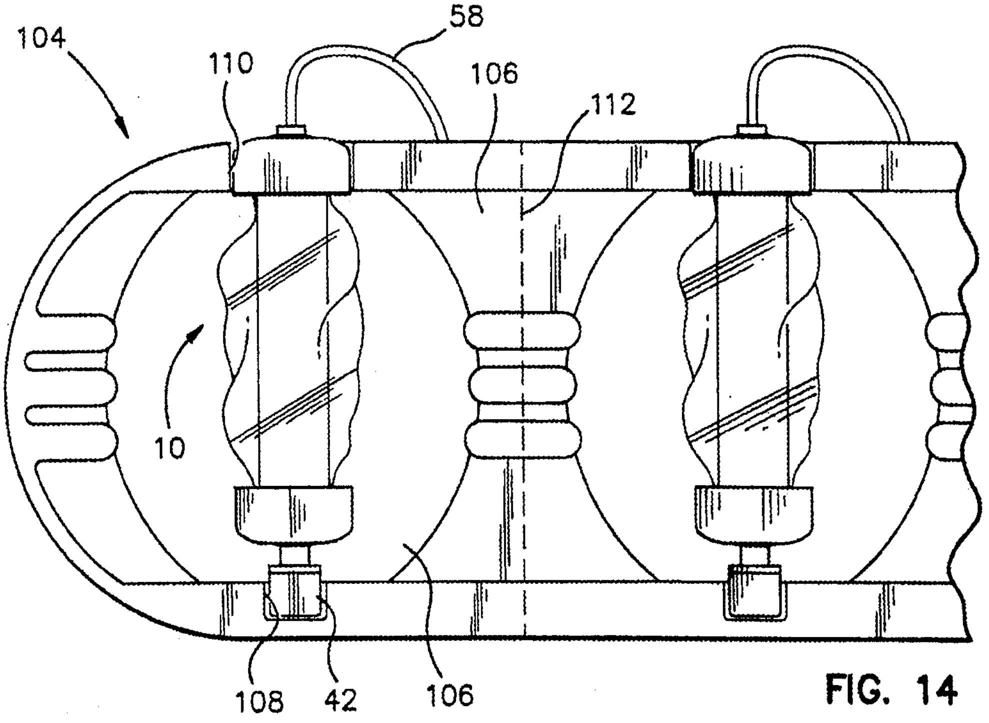

104
58
110
106
112
10
108
42
106

FIG. 14

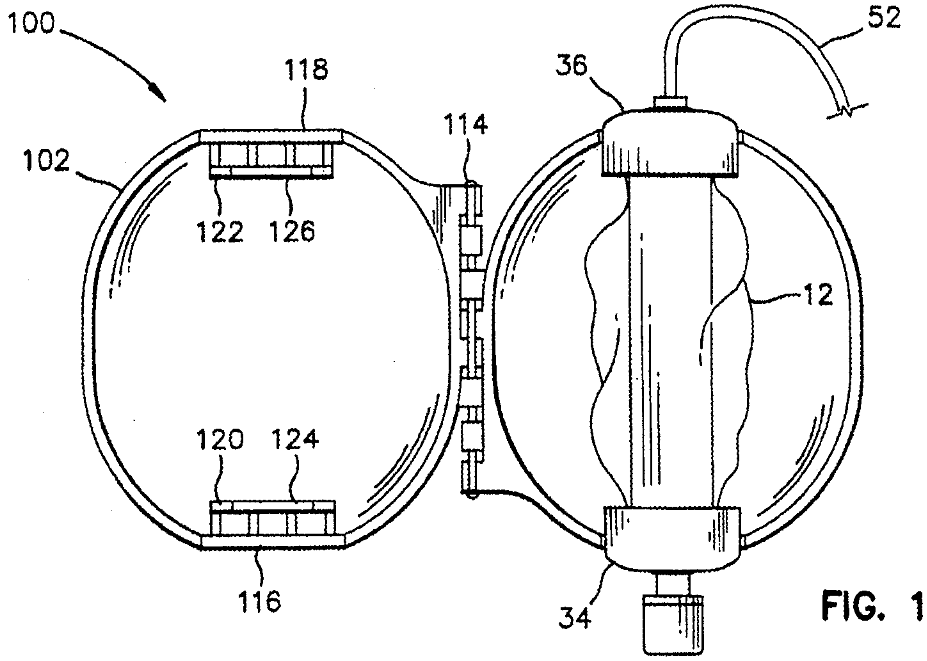

100
118
114
36
52
102
122
126
12
120
124
116
34

FIG. 12

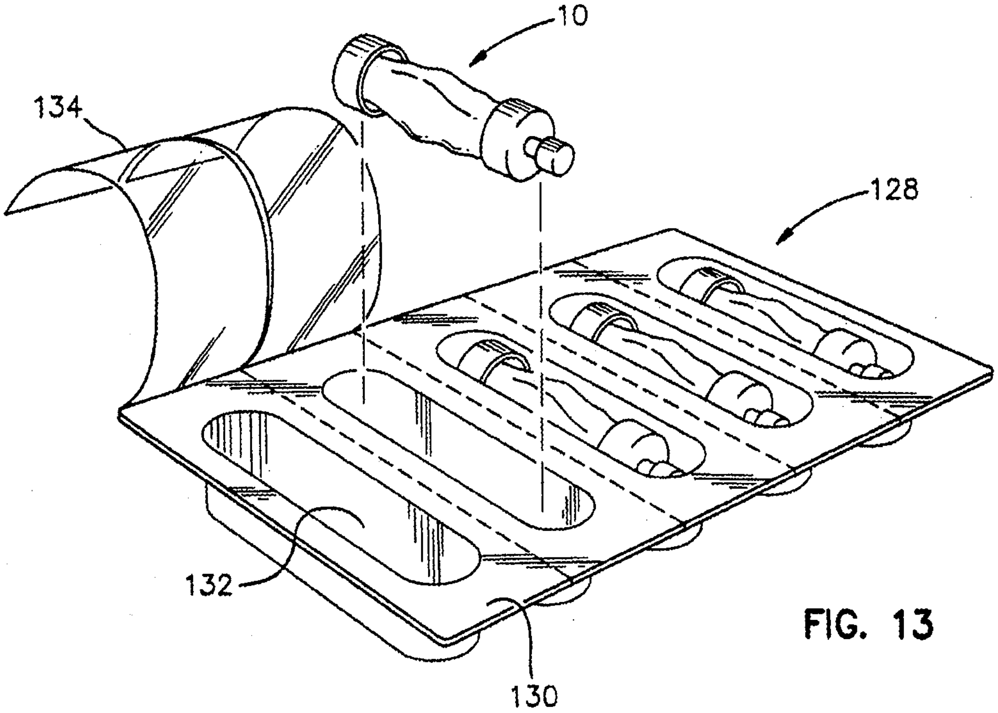

10
134
128
132
130

FIG. 13

COMPACT COLLAPSIBLE INFUSION APPARATUS

BACKGROUND OF THE INVENTION

The present invention relates to liquid dispensing apparatus and pertains particularly to an improved infusion apparatus for delivering intravenous drugs at a controlled rate to a patient.

It is often necessary to intravenously supply patients with pharmaceutically active liquids at a controlled rate over a long period of time. It is desirable that this be accomplished while the patient is in an ambulatory state. A few devices have been developed in the past for accomplishing this purpose.

The prior art devices typically comprise an elastic bladder forming a liquid container mounted in an elongated cylindrical housing, and having a flow control valve or device and tubing for supply of the liquid to the patient. These devices are constructed with the cylindrical form in order to provide a compact arrangement. The elastic walls of the bladder are forced to expand along the walls of the cylindrical housing when filled with the liquid, and provide the pressure for expelling the liquid. These prior art devices are typically filled by hand by means of a syringe which often require an inordinate amount of force.

Another drawback to the prior art devices is that the bladder is forced to expand into an unnatural elongated configuration along the housing walls as the container is filled. As a result of this unnatural configuration, the pressure of the bladder and the flow rate of the unit varies widely with the volume of liquid therein. Therefore, they do not have a reasonably stable pressure and flow rate over the infusion period.

Prior U.S. Pat. Nos. 5,080,652, dated Jan. 14, 1992 and 5,105,983, dated Apr. 21, 1992 of common assignment herewith disclose recently developed improved infusion devices. These devices have an inflatable elastic bladder that is allowed or inflate naturally at a substantially uniform pressure. A hard protective housing accommodates natural spherical inflation of the bladder to its rated capacity or volume.

While these improved devices are portable and convenient to use, one objection is that the housing is rigid and space consuming. This increases the cost of packaging, storage and shipment. It also increases the cost of manufacture because the housing must also be sterilized. Therefore, it would be desirable to have a housing that is collapsible and/or reusable.

It is desirable that the housing of an inflatable bladder infuser be compact and inexpensive to manufacture and ship.

Accordingly, it is desirable that an improved infuser apparatus be available.

SUMMARY AND OBJECTS OF THE INVENTION

It is the primary object of the present invention to provide an improved liquid infuser apparatus.

In accordance with a primary aspect of the present invention, a liquid infuser apparatus comprises an elastic reservoir comprising an elastic sleeve mounted on a substantially cylindrical support member mounted within a spherical chamber of a collapsible housing.

Another aspect of the invention includes a protective rigid outer housing in which the infuser apparatus may

be removeably placed either in the filled or unfilled condition.

A further aspect of the invention comprises a kit of a plurality of the infusers packaged with a single reusable protective rigid outer housing in a compact arrangement.

BRIEF DESCRIPTION OF THE DRAWING

The above and other objects and advantages of the present invention will become apparent from the following description when read in conjunction with the accompanying drawings wherein:

FIG. 1 is a top plan view of a preferred embodiment of the invention;

FIG. 2 is a view taken on line 2—2 of FIG. 1;

FIG. 3 is an enlarged detailed view of a portion of FIG. 2 showing the retaining cap and coupling;

FIG. 4 is an enlarged detailed top view of the check valve assembly of the embodiment of FIG. 1;

FIG. 5 is a section view taken on line 5—5 of FIG. 4;

FIG. 6 is a side elevation view showing a filled infuser in a rigid housing;

FIG. 7 is a top plan view of a kit embodiment of the invention;

FIG. 8 is a section view taken generally on lines 8—8 of FIG. 7;

FIG. 9 is a top plan view of a filling jig for use with the invention;

FIG. 10 is a section view taken generally on lines 10—10 of FIG. 9;

FIG. 11 is a side elevation view of an alternate embodiment of a rigid housing;

FIG. 12 is a side elevation view of a further embodiment of a rigid housing;

FIG. 13 is a perspective view of an alternate shipping package embodiment of the invention; and

FIG. 14 is a top plan view of a combined package and rigid housing embodiment of the invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Referring to the drawings, and particularly to FIGS. 1 and 2, there is illustrated an exemplary embodiment of an infuser pump in accordance with the invention. The infuser pump, designated generally by the numeral 10, is collapsible and comprises an outer collapsible substantially non-stretchable housing or shell 12, protectively mounted over a combined reservoir and support assembly constructed substantially like that set forth in U.S. Pat. Nos. 5,080,652, dated Jan. 14, 1992 and 5,105,983, dated Apr. 21, 1992, both of which are incorporated herein by reference as though fully set forth.

The collapsible housing 12 has a substantially spherical configuration for confining and guiding the inflatable reservoir or bladder into a concentric position around the central support member, and enabling it to expand naturally in a spherical configuration as will be described. The collapsible housing 12, as been seen in FIG. 2, has coaxial openings defined by tubular sleeve extensions 14 and 16 through which the ends of a central support member 18 extends.

An elastic membrane or bladder assembly 20 forming an inflatable reservoir, such as described in the aforementioned patents, is mounted on the cylindrical support member 18. The bladder assembly 20 may be a single sleeve or multiple sleeves, as set forth in the prior patents. This is preferably with an inner sleeve being a chemically inert sleeve, and the outer sleeve or sleeves being highly elastic.

The central cylindrical support member or mandrel **18** includes circular grooves only one of which, **22** is shown, at the ends thereof into which portions of the sleeve **20** and housing **12** are biased by means of a pair of O-rings, only one of which, **26**, is shown. The collapsible housing **12** is preferably a non-stretch blow molded housing of from five to ten mils. in thickness and made of a material such as polyurethane, PVC film, and/or polyethylene and is transparent. This forms a simple inexpensive compact unit with a certain amount of protection for the elastic reservoir.

Certain applications may require a tougher collapsible housing. In such cases, the housing should be transparent, UV stable, flexible and highly resistant to puncturing. The housing would be constructed of a material such as tough composites in a flexible form such as a fabric. Examples of such material are available under the trademark Kevelar.

The ends of the central support member **18** include reduced diameter extension **30** and **32**, with bayonette type couplings for releasably coupling cup-shaped caps **34** and **36** which extend over and protectively cover the O-ring connections or clamping of the elastic bladder and collapsible housing to the support member. Referring to FIG. **3**, the bayonette connection for member **32** and **36** is illustrated. The member **32** has flat sides **38** for receiving a similarly shaped opening **40** in cap **36**, with the cap **36** having inwardly extending flanges forming the flat sides which extend behind shoulders of the extension **32** for retaining the cap in place upon rotation of the cap ninety degrees relative to the member **32**. This forms a quick and easy assembly construction for the protective cap.

The support member **18** has an inlet or fill port **42** on one end which communicates with a coaxial passage **44**, and a transverse passage **46** in which is mounted a check valve **48**. The cross bore **46** communicates with passage **44** and inlet port with the interior of the elastic bladder or sleeve **20** and thus the interior of the inflatable reservoir. The check valve **48** (FIGS. **4** and **5**) is of a generally cylindrical outer shape, with a square bore **50** extending from one end and closed at the other forming a cup-shaped structure. The check valve is constructed of an elastomer, such as silicone, and collapses inward to allow filling and erects to its normal configuration to prevent back flow. The square bore configuration of the bore insures that it returns to its normal configuration and does not remain collapsed.

An outlet port through end **32** communicates with a passage **54** that extends coaxially from the other end of the support member **18**, and communicates with a cross bore or port **56** with the interior of the elastic bladder or reservoir **20**. A tubing set, including a tube **52** having a filter **58** and a connector **60** at the end, provides a means for connecting and dispensing a fluid to a site, such as a vein of a patient.

The collapsible infuser apparatus of FIGS. **1** and **2** comprises a compact and inexpensive disposable unit. It has a compact configuration, with a collapsed diameter no greater than the outer diameter of the caps **34** and **36**. For this reason, it is convenient to package in multiple unit kits as will be subsequently described. In addition, it may be temporarily housed during use in a protective hard shell housing as illustrated in FIG. **6**.

Referring to FIG. **6**, a simple exemplary protective housing **62**, in the illustrated embodiment, having a generally cylindrical configuration with an open top and a diameter, can receive and accommodate the fully expanded or filled reservoir during use. This provides a reusable protective housing that may be provided with a kit of multiple infuser units. The protective housing is preferably formed of a high strength material such as polycarbonate. The filled infuser may be placed in the protective housing **62** and placed in a carrying pouch, thereby providing protection against accidental undue pressure or accidental puncturing of the reservoir bladder. The inflatable bladder or reservoir is very susceptible to puncturing when in the inflated condition. For this reason, it is desirable that it be within a puncture resistive housing when inflated. The housing **62** may have other configurations and may have a removable cover if desired (see FIGS. **11** and **12**).

Referring to FIGS. **7** and **8**, a kit of multiple infusers, in accordance with the invention, is packaged as a kit for convenient use for a seven day period, for example. As illustrated in FIGS. **7** and **8**, the kit comprises a generally rectangular opened top box or container **64** of a very thin, substantially rigid plastic material having a peripheral flange **66** for attachment of a suitable cover. The container forms a chamber in which is placed a styrofoam support block **68** having a plurality of bores **70** spaced around the periphery thereof for receiving the inlet end and cap portion of a plurality of the infusers **10**.

A cylindrical bore **72** in the center of the block **68** receives the cylindrical housing **62** in an upright position. Positioned within the housing **62** is a circular or cylindrical styrofoam block **74** having three bores **76** similar to the bore **70** for receiving the filler ends of three infusers **10**. This provides a kit of seven infuser units providing a week's supply.

These kits are easily packaged at a factory and shipped to a hospital or to a pharmacist who removes and fills the infusers and supplies them along with a reusable housing **68** to a patient for home use. The patient then uses each of the infusers in consecutive order and disposes of them when used. This provides a compact convenient package. The package has a typical size of approximately 4 ¼ inches high and 3¾ inches on a side. This takes up slightly more than the space of a single unit of the prior design having a hard shell. For example, a one-hundred milliliter hard shell unit is about 4 inches in length and about 2½ to 3 inches in diameter. Thus, a package of seven of the present units takes about sixteen cubic inches of space versus about twelve cubic inches for one of the prior units.

Referring to FIGS. **9** and **10**, a convenient filling rack for an infuser of the present design is illustrated, designated generally by the numeral **78**. The rack is molded of a suitable plastic material and is formed within the illustrated embodiment with **7** (or any other suitable number) identical holder positions. Each holder position has a central cavity **82** for receiving and enabling expansion of the bladder, an upper recess **84** for receiving a filler end cap **34**, and a lower recess **86** for receiving a cap **36**. The panel **80** has a forward leg **88**, with a foot **90** to hold the support panel in an included position for ease of use. The pharmacist may simply load the rack with a plurality of infusers and either fill them in sequence or simultaneously as desired.

Referring now to FIG. **11**, an alternate embodiment of an outer housing or shell is illustrated and designated generally by the numeral **92**. This outer housing has a somewhat spherical configuration with outer spherical walls 94 and a lower end which may have an opening 96 for exposing an inlet or fill port 42 for filling. A removable cap 98 provides a closure for an opening 100 in the top of the housing. The cap includes a central opening 102 for extension of a tubing set 58. The cap 98 may be attached in any suitable manner such as friction fit, bayonette type coupling, threads or the like to the housing.

The opening 100 in the upper end of the housing walls may be sufficiently large to enable a filled infuser unit, as disclosed in FIGS. 1 and 2, to be inserted into the housing. This provides a reusable housing which may also include a cap or closure for protectively closing the unit. In addition, this provides a housing in which the unit without a protective collapsible housing may also be enclosed or housed for filling. In other words, with this unit the collapsible housing 12 of the FIGS. 1 and 2 unit may be eliminated. This provides an alternate compact arrangement wherein multiple compact units may be packaged with a single protective outer housing, and provided to a pharmacist for filling and supplying to patients.

Referring to FIG. 12, an openable spherical shell embodiment of a protective housing is illustrated and designated generally at 100. The housing is constructed of two identical half-shells 102 connected together by a hinge pin 114. Thus, a filled or unfilled infuser may be placed in the reusable protective housing. The shells each have an opening 116 and 118 at each end with an inwardly spaced wall 120 and 122, each having an opening 124 and 126. The end caps 34 and 36 of an infuser are received in the openings 116 and 118, and the central support member 18 is received in the openings 124 and 126. The ends of the infuser unit are thereby exposed for access. The hinge axis extends along a line parallel to an axis defined by the openings in the shell.

Referring to FIG. 13, an alternate embodiment of a packaging system for multiple infusers is illustrated and designated generally by the numeral 128. A base container sheet 130 has a plurality of cavities 132 formed therein for receiving infuser units 10. A cover sheet 134 covers the base sheet and cavities to protectively seal the infuser units in the cavities. The base sheet may be either flexible or somewhat rigid. The base sheet and cover sheet have perforations 136 separating the cavities 132. This enables selective separation of single units from the overall package. Alternatively, the entire cover sheet can be peeled away to provide common access to a plurality of the infuser units.

Referring to FIG. 14, an alternate embodiment of combined packaging and protective housing is illustrated. This package, designated generally by the numeral 104, comprises opposed thin plastic sheets, only one of which 106 is shown, forming mirror images of one another. These opposed sheets have semi-spherical recesses or cavities forming a generally spherical chamber in which a dispensing unit 10, substantially as described in FIGS. 1 and 2, is encapsulated, with an opening or bore 108 through which a filler port or cap 42 extends. The package also provides an opening 110 at the other end for extension of a tubing set 58. The entire package can contain any selected number of units which may be shipped to a pharmacist. The pharmacist may take the package and select and separate an appropriate number of the infusers, fill them and supply them to a patient. The infuser units may be separated along a perforated line 112 of the package such that an individual infuser may be separated from the remainder.

Thus, the unit of FIG. 1 can be effectively packaged in simple and inexpensive packaging for supplying to pharmacists. This form of packaging can also be used without the collapsible housing, such that the unit contains only the inflatable reservoir, and the packaging forms a protective non-collapsible housing. Similarly, the units without the collapsible housing can be used with any of the rigid housings discussed herein.

While we have illustrated and described our invention by means of specific embodiments, it is to be understood that numerous changes and modifications may be made therein without departing from the spirit and scope of the invention as defined in the appended claims.

We claim:

1. A compact portable apparatus for dispensing a liquid under pressure at a substantially constant flow rate over a period of time comprising:

an elongated generally cylindrical support member;

elongated elastic sleeve means mounted and sealingly secured at fixed spaced longitudinal positions on said support member for defining a substantially zero non-pressurized volume pressure reservoir for holding a liquid in a pressurized state for dispensing therefrom;

housing means comprising collapsible non-stretchable housing means for containing said support member and said pressure reservoir for enabling said pressure reservoir to expand naturally and for confining said reservoir to fill concentrically about said support member;

inlet means for introducing a liquid into said elastic pressure reservoir; and

outlet means for dispensing liquid from said pressure reservoir to a selected site.

2. An apparatus for dispensing a liquid under pressure according to claim 1 wherein said collapsible non-stretchable housing means comprises a substantially spherical housing.

3. An apparatus for dispensing a liquid under pressure according to claim 2 wherein said housing means further comprises a generally cylindrical substantially rigid housing having an open end for receiving said support member.

4. An apparatus for dispensing a liquid under pressure according to claim 2 wherein:

said support member is an elongated generally cylindrical mandrel mounted in said housing means and having opposite ends exposed to the exterior of said housing means, said inlet means comprises an inlet port in one end of said mandrel, and said outlet means comprises an outlet port in the other end of said mandrel; and

said housing means is clamped at opposite ends thereof with said elastic sleeve means around opposite ends of said mandrel by an elastic ring.

5. An apparatus for dispensing a liquid under pressure according to claim 1 wherein:

said collapsible non-stretchable housing means is substantially spherical having openings formed in opposite ends thereof by co-extending tubular sleeves; and

said housing means is commonly clamped at opposite ends thereof with said elastic sleeve means around opposite ends of said support member by means of an O-ring extending around said tubular sleeves.

6. An apparatus for dispensing a liquid under pressure according to claim 5 wherein said said O-rings are each

covered by a cup shaped cap removeably attached to the ends of said support member.

7. An apparatus for dispensing a liquid under pressure according to claim 6 wherein said housing means further comprises a generally cylindrical substantially rigid housing having an open end for receiving said support member coaxially therein.

8. An apparatus for dispensing liquid under pressure according to claim 6 wherein said housing means comprises a substantially spherical rigid housing formed of like half-shells hinged together for removably receiving said support member and elastic sleeve.

9. An apparatus for dispensing liquid under pressure according to claim 8 wherein said housing has openings forming stepped recesses for receiving said caps.

10. An apparatus for dispensing a liquid under pressure according to claim 1 wherein:

said housing means comprises a flexible non-stretchable shell having a substantially spherical central chamber with openings formed in opposite ends thereof by co-extending tubular sleeves; and

said housing means is secured at opposite ends thereof with said elastic sleeve means around opposite ends of said support member by means of an O-ring extending around said tubular sleeves.

11. An apparatus for dispensing a liquid under pressure according to claim 10 wherein said said O-rings are each covered by a cup shaped cap removeably attached to the ends of said support member.

12. An apparatus for dispensing a liquid under pressure according to claim 1 wherein said housing means comprises a substantially rigid housing having an opening in one end for receiving said support member coaxially therein.

13. An apparatus for dispensing a liquid under pressure according to claim 12 wherein said rigid housing has a substantially spherical configuration with a removable closure for enabling receipt of said pressure reservoir in a filled condition.

14. An apparatus for dispensing liquid under pressure according to claim 1 wherein said housing means comprises a substantially shperical rigid housing formed of like half-shells hinged together.

15. A compact collapsible infusion apparatus for dispensing a liquid under pressure at a predetermined substantially constant flow rate over a period of time comprising:

an elongated generally cylindrical support member having inlet means including an inlet port in one end of said member, and outlet means including an outlet port in the other end of said member;

elongated elastic sleeve means mounted in nonstretched surface contact and sealingly secured at fixed spaced longitudinal positions on said support member for defining a substantially zero non-pressurized volume pressure reservoir for holding a liquid in a pressurized state for dispensing therefrom;

first housing means including a collapsible shell enclosing said support member and said pressure reservoir, said housing having a size and shape for enabling said pressure reservoir to expand naturally and for confining said reservoir to fill concentrically about said support member;

inlet means in one end of said support member for introducing a liquid into said elastic pressure reservoir; and

outlet means in the other end of said support member for dispensing liquid from said pressure reservoir to a selected site.

16. An apparatus for dispensing a liquid under pressure according to claim 15 wherein:

said housing means comprises a flexible non-stretchable shell having a substantially spherical central chamber with openings formed in opposite ends thereof by co-extending tubular sleeves; and

said housing means is secured at opposite ends thereof with said elastic sleeve means around opposite ends of said support member by means of an O-ring extending around said tubular sleeves.

17. An apparatus for dispensing a liquid under pressure according to claim 16 wherein said housing means further comprises a generally cylindrical substantially rigid housing having an open end for receiving said support member coaxially therein.

18. Apparatus for dispensing a liquid under pressure according to claim 16 further comprising a cup shaped cap removeably attached to each end of said support member for protectively covering said O-rings.

19. An apparatus for dispensing a liquid under pressure according to claim 18 wherein said housing means comprises a substantially rigid housing having an opening in one end for receiving said support member coaxially therein.

20. An apparatus for dispensing liquid under pressure according to claim 16 wherein said housing means further comprises a pair of substantially semi-spherical pivotably connected half-shells forming a substantially spherical rigid housing.

21. An apparatus for dispensing liquid under pressure according to claim 20 wherein said housing has openings forming stepped recesses for receiving said caps.

22. An apparatus for dispensing liquid under pressure according to claim 20 wherein said housing has openings forming stepped recesses for receiving said caps.

23. A medical infusion kit having multiple apparatus for dispensing multiple dosages of a liquid under pressure at a substantially constant flow rate over a period of time comprising:

a plurality of substantially identical collapsible infusion devices, each having a collapsible housing having a chamber for containing a pressure reservoir, an elongated generally cylindrical support member disposed in and extending through said chamber, an expansible elastic pressure reservoir mounted on said support member in said chamber for holding said liquid under pressure during dispensing thereof, said elastic pressure reservoir comprises an elastic sleeve snugly mounted over said support member in said chamber for defining a pressure reservoir for holding a liquid in a pressurized state for dispensing therefrom, inlet means in one end of said support member for introducing a liquid into said elastic sleeve;

a substantially rigid housing having an open end for removeably receiving said infusion devices coaxially therein in a filled condition; and

outlet means in the other end of said support member for conveying a liquid from said pressure reservoir to a selected site.

24. An infusion kit according to claim 23 wherein said collapsible housing comprises a flexible non-stretchable shell having a substantially spherical central chamber with openings formed in opposite ends thereof by co-extending tubular sleeves; and

said shell is secured at opposite ends thereof with said elastic sleeve around opposite ends of said support member by means of an O-ring extending around said tubular sleeves.

25. An infusion kit according to claim 24 further comprising a cup shaped cap removeably attached to each end of said support member for protectively covering said O-rings.

26. An infusion kit according to claim 25 wherein wherein said plurality of infusion devices are from five to seven in number.

27. A compact portable dispensing apparatus for dispensing a liquid under pressure at a substantially constant flow rate over a period of time comprising:

an elongated substantially cylindrical support member;

elongated elastic sleeve means mounted on and sealingly secured at fixed spaced longitudinal positions on said support member for defining a pressure reservoir for holding a liquid in a pressurized state for dispensing therefrom;

housing means comprising a substantially spherical rigid housing formed of like half-shells hinged together for removeably containing said support member and said pressure reservoir for enabling said pressure reservoir to expand naturally and for confining said reservoir to fill concentrically about said support member;

inlet means for introducing a liquid into said elastic pressure reservoir; and

outlet means for dispensing liquid from said pressure reservoir to a selected site.

28. An apparatus for dispensing a liquid under pressure according to claim 27 wherein:

said housing means comprises a flexible non-stretchable shell having a substantially spherical central chamber with openings formed in opposite ends thereof by co-extending tubular sleeves; and

said housing means is secured at opposite ends thereof with said elastic sleeve means around opposite ends of said support member by means of an O-ring extending around said tubular sleeves.

* * * * *

PROOF OF SERVICE

I am a citizen of the United States of America and I am employed in San Diego, California. I am over the age of 18 and not a party to the within action. My business address is 550 West C Street, San Diego, California. On March 6, 2008, I caused **DECLARATION OF BORIS ZELKIND IN SUPPORT OF PLAINTIFF'S MOTION TO CONSOLIDATE** to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following person(s):

Norbert Stahl, Esq.
STAHL LAW FIRM
nstahl@patentlawservice.com

I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Executed on March 6, 2008 at San Diego, California.

Megan Ptacin

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